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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/695,151

10/27/2003

Stephen C. Porter

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EXAMINER

HOUSTON, ELIZABETH

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

08/07/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/695,151	Applicant(s) PORTER, STEPHEN C.	
	Examiner ELIZABETH HOUSTON	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16,20-30,32-38 and 40-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16,20-30,32-38 and 40-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 1-5, 10, 12, 15, 16, 20, 30, 32, 33 and 40 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/694927 in view of Martinez (US 2004/0098028). The claims of the copending application claim all the elements of the

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instant application including an occlusive member that is a coil having an axial lumen, an active element that comprises an agent carrier that contracts. The claims of the copending application do not disclose that the active carrier is a hydrogel or that the active element is contained entirely within the lumen. Martinez discloses a similar occlusive element having a coil with axial lumen, and an active element that includes a hydrogel where the active element is entirely within the lumen of the coil. It would have been obvious to one having ordinary skill in the art at the time of the invention to apply the known technique of incorporating the active agent entirely within the lumen to the known device of the copending claims and the combination would have yielded predictable results.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. **Claims 1-8, 14-16, 20, 21, 24, 27, 30, 31, 34-36 and 40-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ken (US 6,193,728) in view of Kupiecki (US 5,669,931) in view of Rosenthal (US 7,066,904)**

6. Ken discloses vaso-occlusive device comprising an elongate occlusive member (102,202), which is a coil defining a longitudinal axis having an elongate axial lumen

and an active element (108,214) having a pre-deployment configuration carried entirely within the lumen. No portion of the pre-deployed active element is located outside of the lumen. The active element is configured to cause the occlusive member to substantially retain its shape when deployed. The active element is secured to the occlusive member by an adhesive at one or both ends and at one or more locations along the length of the occlusive member (Col 5, lines 1-3). The active element has an elongate shape (Fig 1A) and a coil shape (Fig. 1C). The active element comprises shape memory alloy or a shape memory polymer (Col 5, line 31 and Col 6, line 46-48). The active element can be a fiber comprising protein (Col 6, line 64).

7. Ken does not disclose that the active element contracts.

8. However, Kupiecki teaches a vaso-occlusive device where the interior is filled with a drug material that can be advantageous for inducing thrombism or for treating surrounding tissue (C 6:L 11-17).

9. Rosenthal teaches that one method of drug delivery incorporates immobilizing a drug within a hydrogel to control the release of the drug (C1: L47-59). The hydrogel can expand or contract in order to release the drug (bioactive agent) (Col 6, line 55-64). The hydrogel is a polymer hydrogel that is swollen with an aqueous ionic solution that will diffuse out of the gel upon contact with blood (Col 2, lines 32-57). The polymer can be polymethacrylate (Col 3, line 37). The polymer is thermoresponsive (Col 3, line 60).

10. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate a hydrogel for carrying a drug within the lumen of the occlusive coil as taught by Kupiecki and Rosenthal. Doing so would allow better control

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over the delivery drugs for treating the tissue and inducing thrombism. The combination results in the device of Ken having a stretch-resisting element (108) coated with the drug filled hydrogel which reads on the claimed active element. The hydrogel part of the active element will contract to a deployed configuration without the application of mechanical force when placed in the body to deliver the drug as taught by Rosenthal. The stretch resisting element part of the active element will cause the occlusive member to “substantially” retain its shape when deployed in a body cavity. Note that the claimed invention does not require the actual act of the active element contracting to cause the coil to retain its shape since during the act of the active element contracting, the coil will also be moving and reshaping, thus not retaining its shape. Rather, the claimed invention only requires that the final product of a contracted active element/hydrogel causes the coil to retain its shape since it is after the act of contracting and reshaping the coil that the active element causes the coil to retain its shape.

11. Claims 9-13, 22-26, 28, 29, and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ken (US 6,193,728) in view of Kupiecki (US 5,669,931) in view of Rosenthal (7,066,904) as applied above and further in view of Sawhney (US Pub 2001/0046518).

12. Ken modified by Kupiecki and Rosenthal discloses the invention substantially as claimed as stated above except for the material that makes up the hydrogel.

13. Sawhney discloses a hydrogel used for delivery of therapeutic agents. The hydrogel comprises polypropylene glycol or poly-hydroxyalkyl methacrylate (Para 37, 38). The hydrogel comprises polysaccharides, hyaluronic acid or heparin (Para 35).

The hydrogel further comprises chemical cross-linking agents (Para 31). The hydrogel is thermoresponsive (Para 40). The hydrogel comprises a polyelectrolyte (Para 38) and undergoes an ionic concentration induced shape change (Para 40). The active element can be a fiber (Para 37 and 62), which undergoes a thermally induced phase change or a pH induced phase change (Para 40). The active element is activated within about 10-20 minutes of being placed in a body (Para 28).

Ken modified by Kupiecki and Rosenthal provides the base of an occlusive coil with a core member that uses hydrogel to deliver bioactive agent. Sawhney provides the teaching of materials and characteristics of hydrogels. It would have been obvious to one having ordinary skill in the art at the time of the invention to enhance the modified device of Ken modified by Kupiecki and Rosenthal with the different materials and characteristics of hydrogels, since the teachings were made part of the ordinary capabilities of one skilled in the art based upon the teachings of Sawhney. It has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

Response to Arguments

Applicant's arguments, see Pre-appeal Request, filed 03/11/08, with respect to claims 1-16, 20-30, 32-38, 40-42 have been fully considered and are persuasive. The rejection of 12/11/07 has been withdrawn.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH HOUSTON whose telephone number is (571)272-7134. The examiner can normally be reached on M-F 9:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on 571-272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

eh

/Todd E Manahan/
Supervisory Patent Examiner, Art Unit 3731